"COMPARATIVE STUDY BETWEEN RETROGRADE URETHROGRAPHY AND MAGNETIC RESONANCE URETHROGRAPHY IN EVALUATING MALE URETHRAL STRICTURE DISEASE"

Dissertation submitted for partial fulfilment of requirements of

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&
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AUGUST-2013

CERTIFICATE

This is to certify that **Dr.R.Sukumar** has been a post graduate student during the period August 2010 to July 2013 at Department of Urology, Govt Kilpauk Medical College, & Hospital, Chennai.

This Dissertation titled **"COMPARATIVE STUDY BETWEEN RETROGRADE URETHROGRAPHY AND MAGNETIC RESONANCE URETHROGRAPHY IN EVALUATING MALE URETHRAL STRICTURE DISEASE"** is a bonafide work done by him during the study period and is being submitted to the Tamilnadu Dr. M.G.R. Medical University in a partial fulfilment of the MCh Branch IV Urology Examination**.**

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DECLARATION

I Dr.R.Sukumar solemnly declare that this dissertation entitled, "COMPARATIVE STUDY BETWEEN RETROGRADE URETHROGRAPHY AND MAGNETIC RESONANCE URETHROGRAPHY IN EVALUATING MALE URETHRAL STRICTURE DISEASE" is a bonafide work done by me at the Department of Urology, Govt Kilpauk Medical College and Hospital during the period 2010 – 2013 under the supervision of Professor P.Vairavel,D.G.O,M.S,MCh,Department of Urology, Govt Kilpauk Medical College and Hospital.

This dissertation is submitted to The Tamil Nadu Dr.M.G.R Medical University, towards a partial fulfilment of requirement for the award of MCh Degree Branch IV Urology**.**

Place: Chennai
Date : 25.03.2013 **Dr.R.SUKUMAR**

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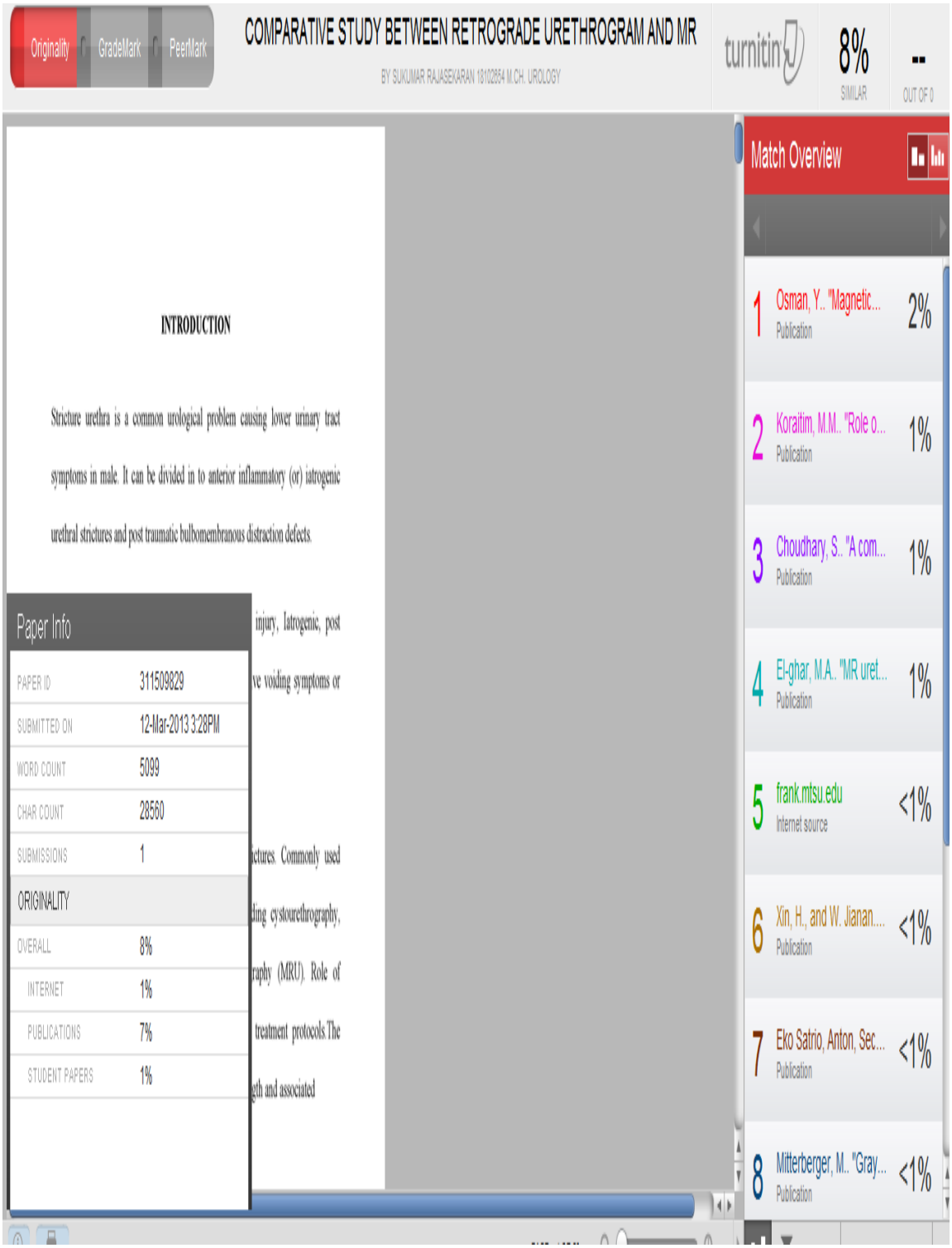
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INTRODUCTION
Stricture urethra is a common urological problem causing lower urinary tract symptoms in male. It can be divided in to anterior inflammatory (or) iatrogenic urethral strictures and post traumatic bulbomembranous distraction defects.
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LIST OF ABBREVIATIONS

KMCH	Kilpauk Medical College & Hospital
GRH	Govt. Royapettah Hospital
RUG	Retrograde Urethrography
MRU	Magnetic Resonance Urethrography
PFUDD	Pelvic Fracture Urethral Distraction Defect
Ant	Anterior
Post	Posterior
BNE	Bladder Neck Elevation
BNI	Bladder Neck Incision
VCUG	Voiding CystoUrethroGraphy
SUG	Sonourethrography
LOCM	Low Osmolar Contrast Media
SURG	Surgery
GUD	Guided Urethral Dilatation

INTRODUCTION

Stricture urethra in male is a common urological problem causing lower urinary tract symptoms. It can be divided in to anterior inflammatory (or) iatrogenic urethral strictures and post traumatic bulbomembranous distraction defects.

It can be caused by inflammation or trauma (pelvic injury, Iatrogenic, post catheterization). Strictures usually present with obstructive voiding symptoms or urinary tract infections and occasionally retention.

Various modalities have been devised to diagnose strictures. Commonly used methods include retrograde urethrography (RUG), voiding cystourethrography, Sonourethrography and Magnetic Resonance urethrography (MRU). Role of imaging in strictures is significant in determining the treatment protocols.The treatment options and approach depends upon the site, length and associated spongiofibrosis and fistula.

The gold standard imaging technique is RUG which is readily available, simple and cost effective. Disadvantages include its invasive nature, contrast allergy, inaccurate estimation of stricture length and does not show the spongiofibrosis.

Recent non invasive tests have been developed to circumvent the problems of RUG, like Sonourethrography and Magnetic resonance urethrography that do not require injection of contrast media. Though noninvasive each has its own disadvantages. Sonourethrography which is not useful in the evaluation of posterior urethra and the disadvantage of MR Urethrography is its cost and availability.

This study is done to compare the clinical relevance of Retrograde urethrography and Magnetic resonance urethrography in male urethral stricture disease to guide further management.

AIM

To compare the clinical relevance of retrograde urethrography and Magnetic resonance urethrography in male urethral stricture disease for planning the surgical management

REVIEW OF LITERATURE

D.E.Andrich and A.R.Mundy[1] described the stricture as narrowing of urethral caliber due to scar following injury (or) infection. Nielsen and Nordling[2] on the basis of study done over 4000 male urethradescribed stricture as urethral lumen less than 22Fr size,and found that stricture would be symptomatic only if the lumen reduces to 18Fr.

The retrograde urethrogram was set as gold standard imaging modality for the diagnosis of stricture urethra in 1910, by Cunningham.[3]But RUG was not found to be useful in evaluation of posterior urethral strictures.

Gallentine ML, Morey AF concluded that in posterior urethral evaluation retrograde urethrogram clubbed with voidingcystourethrography was very informative to depict the proximal extent of the stricture when compare to RUG alone.[4]

Nash PA and McAninch J[5]evaluated anterior urethral stricture based on retrograde urethrogram and found that the actual stricture length determined endoscopically correlated with penile urethral stricture better than that of bulbar urethral stricture.

According to Syed Mamun Mahmud et al[6], the sensitivity & specificity of RUG for the diagnosis of urethral stricture was 91% &72% and by MRU 100%

In 1987,Friedburg&Wimmer studied the usefulness of Magnetic resonance Urography and concluded that the MRU provided more findings than conventional radiology and USG.[7]The findings were confirmed by Garcia-Valtuille[8]in which MR Urography was found to be a safe diagnostic tool with high quality images of urinary system than the other imagingmethods.

MM Oh et al [9] in their study of 25 patients concluded that MR Urethrography was more effective in evaluation of obliterative posterior urethral stricture than retrograde urethrography combined with voiding cystourethrography.

Eaton J et al published the currentstatus of imaging of urethra in 2005.They quoted that the MRI plays an important role in the diagnosis of various urethral diseases like fistula,stricture,tumor and also traumatic urethral stricture.[10]

Jeong-ah ryuet al. concluded that the imaging modalities using contrast agents like RUG ,eventhough useful in imaging of urethral anatomical abnormalities,have limited role in evaluation of adjacent structures. But the Magnetic resonance imaging of urethra was very much useful to evaluate the urethral abnormalities and its adjacent structures with high quality images.[11] MR Urethrography was useful in the evaluation of internal organs, diagnosis of fistula, sinus tract and periurethral abscess. In urethral trauma it was helpful to know the site, length and severity. In urethral tumors Magnetic resonance imaging can provide local staging of tumors.

Moon-Hae Choi and colleagues studied the role of MRI in fracture penis. They concluded that it was very useful in showing tear in the tunicaalbuginea, cavernosal hematoma and urethral rupture, because of its multiplanar imaging capability.[12]

Comparative study between MR Urethrography and ascending urethrography and sonourethrography was performed by MA El-Ghar et al. The sensitivity, specificity for diagnosing anterior urethral stricture by RUG was 91% & 90% and 89% & 91.7% for posterior urethra. By MRU it was 91.7% (ant &post). In Sonourethrography,the accuracy was 100% in anterior

urethra, 60% in post urethra.MRU diagnosed all the cases of anterior and posterior stricture with exact delineation of its length with100% sensitivity, 91.7% specificity and 95% overall accuracy.

This study concluded that both RUG &MRU had equal results regarding site and length of strictures.MRU had more accuracy in posterior urethra and superior in showing associated pathologies.[13]

Osman Y compared ascending urethrography and MR Urethrography in male urethral stricture patients. Patients were subjected to surgical procedures (open/endoscopic) and the radiological findings were compared with operative findings. Both modalities showed almost the same accuracy in the diagnosis of Stricture(85%).Additionally another 35% of lesions were shown in MR urethrography like bladder growth, site of urethro rectal fistula, spongiofibrosis and tumors, which were not possible in RUG. The length of the stricture measured correlated accurately to the surgical length in MR urethrography.[14]

The Posterior urethral traumatic injury was evaluated with MRU byY Narumi et al. They concludedthat MR helped to know the correct length of the urethral defect and the prostatic displacements, which guided the surgeons in surgical procedures. The study also proposed that the lateral andsuperior displacement of prostate may be the cause for impotence.[15]

Deukjae sung et al studied 12 patients with stricture disease and compared MRU with RUG clubbed with VCUG in obliterative urethral stricture. They concluded that the result of MRU gave the accurate length of the stricture and linear correlation which is not correct in RUG clubbed with VCUG. [16]

Bircan MK, Sahin H, Korkmaz K et al. performed a study to compare the efficiency, complications of retrograde urethrography and urethroscopy in 38 male patients . 30 patients had the same findings in both procedures. In 8 patients the RGU did not correlate with urethroscopy. This study concluded thatthe results of RGU were misleading, when it was not combined with urethroscopy. [17]

Pavlica P, Barozzi L, Menchi I et al used RUG,SUG and MR Urethrography to study the anterior urethral anatomy and to diagnose periurethral fibrosis, diverticula, and tumors. Additional information was provided by MR urethrogram which was not possible in other modalities. [18]

Koraitim MM,Reda IS and colleagues studied the usefulness of MRI in the assessment of posterior urethral distraction defects in 21 male patients. The MRI and urethrographic findings were compared and correlated with the

operative findings.Preoperative MRI provided correct length of the urethral defect, type and degree of prostatic displacement, site and density of scar tissue. [19]

Choudhary S, Singh P et al[27], conducted the study to compare the sonourethrography and retrograde urethrography in evaluation of anterior urethral strictures. They concluded that, in the estimation of stricture length, RGU showed a lower sensitivity (60-80%) when compared with sonourethrography (73.3-100%). Spongiofibrosis was detected by sonourethrography with a sensitivity of 77.3-83.3%. RGU and sonourethrography were equally efficacious in detection of anterior urethral strictures

IMAGING OF URETHRA

Urethra can be imaged with retrograde urethrogram, opposing urethrogram, Sonourethrogram and MR Urethrogram. [20, 21]

RETROGRADE URETHROGRAM

It is a simple, easy, cheap techniquereadily available, and no need for any preparation.It was first popularized by Cunningham in 1910.

TECHNIQUE

It can be performed in a dynamic or static fashion. In dynamic RUG the film is exposed while contrast is being injected. In static, image is obtained after injection of contrast with clamping of the penis

The patient is placed in supine position, pelvis is oblique 45 degree with the dependent thigh acutely flexed, penis is stretched moderately.Inject 20 cc of contrast (LOCM 30% children & 60% adults) into the urethra.Xray will be taken both before and after the contrast.It can be also performed by keeping a 12 or 14 French Foley catheter, 2 - 3 cm into the urethra and filling the balloon with 2-3 cc of water .[21, 22, 23]

IMAGE ANALYSIS

In normal the bulbar urethra is convex, symmetrical cone shaped, veru appears as filling defect, no narrowing (or) irregularities. In stricture it is narrowed,elongated, asymmetrical and irregular.

Entire urethra should be analyzed for narrowing, irregularities, fistula tracts and site, number, length of the stricture.

Figure 1 - Normal retrograde urethrography

LIMITATIONS

Radiation exposure to testis, contrast allergy, Intravasation of contrast, if high pressure is given during contrast injection

Does not give information about spongio (or) periurethral fibrosis.

Underestimation of length of the bulbar stricture (pelvis is aligned obliquely with respect to the anterior–posterior x-ray beam).

The bulbarurethra is fixed in the same axis as the pelvis. As a result, an‘‘end-on’’ view of bulbar strictures is observed, which reduces their apparent length.[22]

Overestimation of posterior urethral distraction defect

OPPOSING URETHROGRAPHY

It is a combination of retrograde urethrography and voiding cystourethrography. This technique is used to measure the length of posterior urethra in distraction defect. In this technique 300-400ml of contrast mixed with saline instilled into the bladder through suprapubic catheter, 20ml of contrast instilled into the urethra and the patient is advised to make attempt to void and the image is taken

LIMITATIONS

Effective antegrade imaging may not be possible in severe post-traumatic distraction defect, if the bladder neck is not open during voiding film.

Overestimation of posterior urethral distraction defect

SONOURETHROGRAPHY

McAninch JW[24] who was first popularized this technique to overcome the limitations of conventional radiographic techniques

It can be done by injection of saline or jelly into the urethra and evaluate by using 7.5 MHz transducer

It is a noninvasive, simple technique,useful in the assessment of length of the stricture and the extent of spongiofibrosis in anterior urethra

DISADVANTAGE

It depends on the operator

It is not useful for the evaluation of posterior urethral distraction defect

MR URETHROGRAPHY [25]

Bladder is filled with 150-300ml of saline,10ml of jelly is instilled into the urethra and tied by gauze.MR imaging is done with T1,T2-weighted sequences before and after contrast gadopentetate dimeglumine.Images are obtained at axial,coronal,sagittal planes to delineate the length,site,number of stricture and associated periurethral(or)spongiofibrosis.

MATERIALS AND METHODS

30 male patients who were attended the KMCH &GRH urology OPD with symptoms of urethral stricture were taken up for study

STUDY PERIOD – April 2012- Feb 2013

STUDY DESIGN

It is a comparative, Prospective study

INCLUSION CRITERIA

All clinically suspected male urethral stricture patients

EXCLUSION CRITERIA

Acute urethritis

Previous optical internal urethrotomy

Previous urethroplasty

Cardiac pacemaker & implants (in stricture urethra &PFUDD patients)

STUDY PROCEDURES

METHODS

The patients were investigated by Retrograde urethrography and opposing urethrogram(only for PFUDD) followed byMR urethrography.

These patients were subjected to definitive endoscopic or open surgical intervention under anesthesia.The radiological data were compared by endoscopic (or) operative findings in all these patients

TECHNIQUE

RETROGRADE URETHROGRAM

In supine position with pelvis in 45 degree oblique position,with the dependent thigh flexed. 20ml of contrast (60% Iohexol) mixed with normal saline (10+10ml) was taken in a 20ml syringe with a small cannula, which was injected in to the meatus, and x-rays were taken.

In cases of posterior urethral distraction defect , it was combined with opposing urethrogram study to measure the defect

MR- URETHROGRAM

In supine position, 150–300 mL of normal saline was instilled slowly into the bladder (if there was a SPC catheter); 10 mL of sterile jelly was injected into the urethral meatus. The glans sulcus of the penis was gently tied by gauze to avoid escape of the jelly. In the midsagittal plane of the pelvis, the penile shaft was secured with the help of upward traction by tying gauze to the abdomen. MR imaging was performed with the T1, T2-weighted sequences before and 3 minutes after the administration of contrast gadopentetate dimeglumine .The images at different axial, coronal, and sagittal planes were obtained to delineate the entire length of the urethra, with surrounding soft tissue.

IMAGE ANALYSIS

Image analysis was focused on the signal intensity, location, length, and spongiofibrosis and associated pathology.

In anterior urethral stricture, length was measured along the long axis of the fibrotic segment shown as low signal intensity on the sagittal T2-weighted and contrast-enhanced T1-weighted images

In posterior distraction defect,length was estimated by the distance between the proximal limit of the distended distal urethra and the prostatic apex on the sagittal T2-weighted and contrast-enhanced T1-weighted images

PROSTATIC APEX DISPLACEMENT

Superior to inferior – measured between prostatic apex and inferior pubic ramus (>1cm is significant)

Anteroposterior – distance between apex of prostate and urethra at penile bulb

Lateral – distance between apex and bulbar urethra on coronal image

Length on RUG image was determined by measuring the distance between the proximal end of the distal urethra and the distal end of the open proximal urethra. The results of each imaging method were compared with either a definitive urethroscopic procedure (or) description of the surgical findings

FACTORS ANALYSED

Site

Number

Length

Extent of spongiofibrosis

Associated pathology

RESULTS AND ANALYSIS

Total of 30 patients with stricture disease were included in the study.

Age group ranged from 19-58yrs.

10 cases were post inflammatory,14 were post instrumentation and 6 patients had post traumatic distraction defects.

AGE-GROUP -TABLE-1

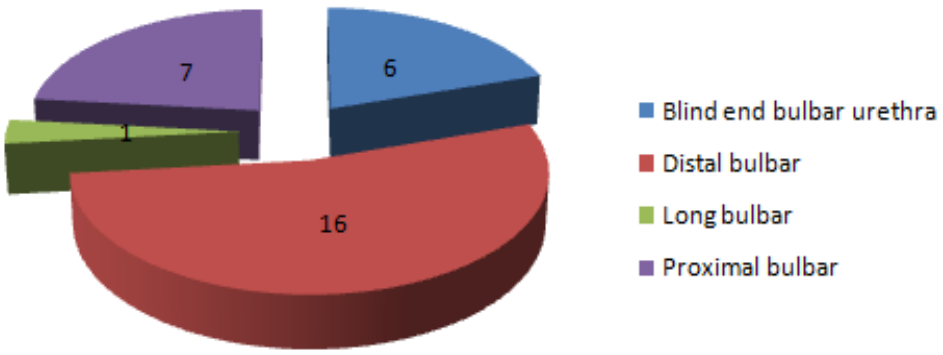
AGE	Years	Urethra		
		Anterior	Posterior	Total
20-30	Count	2	3	5
	% within anterior/ post	8.30%	50.00%	16.70%
	% of Total	6.70%	10.00%	16.70%
30-40	Count	10	1	11
	% within anterior/ post	41.70%	16.70%	36.70%
	% of Total	33.30%	3.30%	36.70%
>40yrs	Count	12	2	14
	% within anterior/ post	50.00%	33.30%	46.70%
	% of Total	40.00%	6.70%	46.70%
Total	Count	24	6	30
	% within anterior/ post	100.00%	100.00%	100.00%
	% of Total	80.00%	20.00%	100.00%

In total 30 cases most of them were above 40 yrs old (46.7%).the mean age was 42.7 yrs.

RUG – FINDINGS

Site of stricture – table -2

RUG site of stricture		Urethra		
		Anterior	Posterior	Total
Blind end bulbar urethra	Count	0	6	6
	% within ant / post	0.00%	100.00%	20.00%
	% of Total	0.00%	20.00%	20.00%
Distal bulbar	Count	16	0	16
	% within ant/ post	66.70%	0.00%	53.30%
	% of Total	53.30%	0.00%	53.30%
Long bulbar	Count	1	0	1
	% within ant / post	4.20%	0.00%	3.30%
	% of Total	3.30%	0.00%	3.30%
Proximal bulbar	Count	7	0	7
	% within ant / post	29.20%	0.00%	23.30%
	% of Total	23.30%	0.00%	23.30%
Total	Count	24	6	30
	% within ant / post	100.00%	100.00%	100.00%
	% of Total	80.00%	20.00%	100.00%

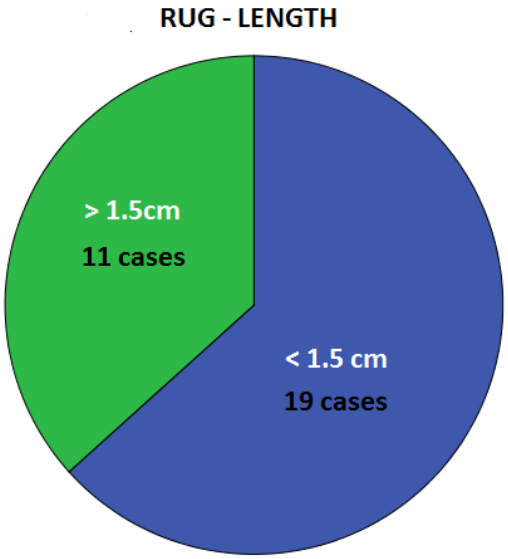


Pie chart no: 1 showing site of urethral stricture in RUG

24 patients had anterior urethral stricture and 6 patients had posterior urethral distraction defect.

RUG – length of stricture –table -3

RUG length		Urethra		
		Anterior	Posterior	Total
<1.5cm	Count	19	0	19
	% within anterior/ post	79.20%	0.00%	63.30%
	% of Total	63.30%	0.00%	63.30%
>1.5cm	Count	5	6	11
	% within anterior/ post	20.80%	100.00%	36.70%
	% of Total	16.70%	20.00%	36.70%
Total	Count	24	6	30
	% within anterior/ post	100.00%	100.00%	100.00%
	% of Total	80.00%	20.00%	100.00%



Pie chart - 2 showing length group of the stricture in RUG

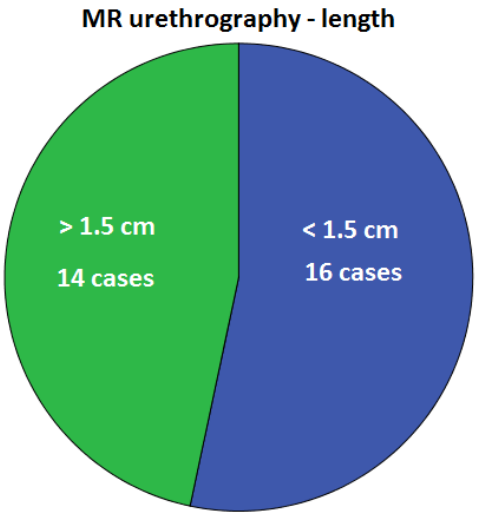
RUG showed 5 long anterior urethral stricture (> 1.5cm), 19 short anterior stricture (<1.5cm), and 6 obliterative bulbar stricture (>1.5 cm) (pie chart – 2).In this 6 cases opposing urethrogram were done to delineate proximal urethra, but the bladder neck was not opened and showed long defect.

In all cases it showed single stricture and in one case mild penile urethra narrowing

MR Urethrography – Findings

Length of stricture –table – 4

MRU length		Urethra		
		Anterior	Posterior	Total
<1.5cm	Count	16	0	16
	% within ant / post	66.70%	0.00%	53.30%
	% of Total	53.30%	0.00%	53.30%
>1.5cm	Count	8	6	14
	% within ant / post	33.30%	100.00%	46.70%
	% of Total	26.70%	20.00%	46.70%
Total	Count	24	6	30
	% within ant / post	100.00%	100.00%	100.00%
	% of Total	80.00%	20.00%	100.00%

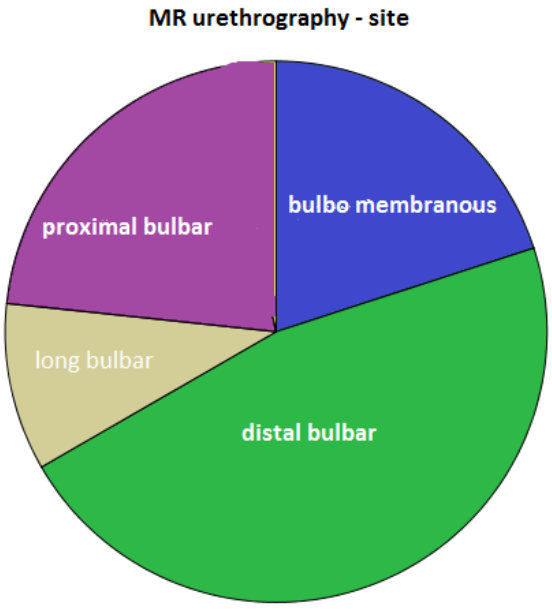


Pie chart – 3 showing length group in MR Urethrography

MR urethrography showed 16 short anterior urethral strictures (<1.5cm), 8 long Anterior stricture (> 1.5cm), 6 long posterior urethral defect (> 1.5)

MRU - site of stricture – table -5

Site of stricture MRU		Urethra		
		Anterior	Posterior	Total
bulbomembranous	Count	0	6	6
	% within ant/ post	0.00%	100.00%	20.00%
	% of Total	0.00%	20.00%	20.00%
Distal bulbar	Count	14	0	14
	% within ant/ post	58.30%	0.00%	46.70%
	% of Total	46.70%	0.00%	46.70%
Long bulbar	Count	3	0	3
	% within ant/ post	12.50%	0.00%	10.00%
	% of Total	10.00%	0.00%	10.00%
Proximal bulbar	Count	7	0	7
	% within ant/ post	29.20%	0.00%	23.30%
	% of Total	23.30%	0.00%	23.30%
Total	Count	24	6	30
	% within ant/ post	100.00%	100.00%	100.00%
	% of Total	80.00%	20.00%	100.00%

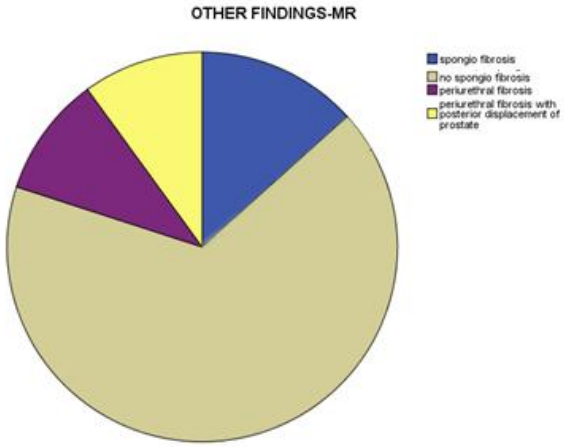


Pie chart -4 showing site of stricture in MR urethrography

14 cases distal, 7 proximal bulbar, 3 long bulbar and 6 cases were bulbomembranous junction.

MRU – other findings –table – 6

OTHER FINDINGS-MRU		Urethra		
		Anterior	Posterior	Total
Nil	Count	20	0	20
	% within anterior/post	83.30%	0.00%	66.70%
	% of Total	66.70%	0.00%	66.70%
Spongiofibrosis,periurethralfibrosis prostatic apex displacement	Count	4	6	10
	% within anterior/ post	16.70%	100.00%	33.30%
	% of Total	13.30%	20.00%	33.30%
Total	Count	24	6	30
	% within anterior/ post	100.00%	100.00%	100.00%



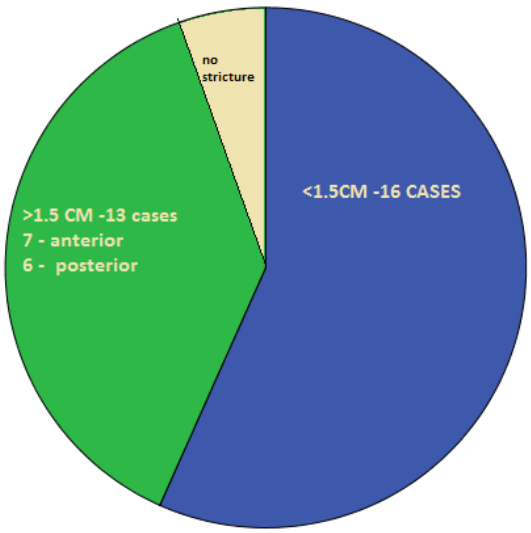
Pie chart-5 showing associated findings in MR Urethrography

In anterior urethra, 4 cases - showed spongiofibrosis, no spongiofibrosis in 20 cases. In posterior urethra, 3 cases – showed periurethral fibrosis, 3cases posterior displacement of the prostate with periurethral fibrosis.

SURGICAL FINDINGS

Length of stricture –table -7

Surgery- length of stricture		Urethra		
		Anterior	Posterior	Total
<1.5cm	Count	16	0	16
	% within anterior/ post	66.70%	0.00%	53.30%
	% of Total	53.30%	0.00%	53.30%
>1.5cm	Count	7	6	13
	% within anterior/ post	29.20%	100.00%	43.30%
	% of Total	23.30%	20.00%	43.30%
No stricture, BNE+ Mild catching in bulbar urethra	Count	1	0	1
	% within anterior/ post	4.20%	0.00%	3.30%
	% of Total	3.30%	0.00%	3.30%
Total	Count	24	6	30
	% within anterior/ post	100.00%	100.00%	100.00%
	% of Total	80.00%	20.00%	100.00%



Pie chart-6 showing surgical length

The surgical procedures were planned according to the findings of the RUG and MRU. In surgery, 16 cases were <1.5cm, 7 cases of anterior urethra were (>1.5cm) and 6 cases were posterior distraction defect (>1.5cm).

In one case there was no stricture,but mild catching in bulbar urethra &mild BNE. Among the 19 short anterior stricture as showed by RUG,2 cases were managed by augmentation urethroplasty,17 cases were treated by VIU,In 5long anterior stricture 3 cases were managed by VIU, 2 cases by augmentation and anastomotic urethroplasty

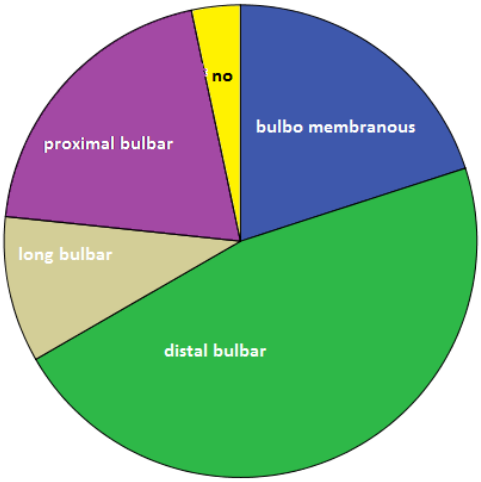
Among the 16 short anterior stricture as showed by MRU, all were treated by VIU, in 8 long anterior stricture 4 treated by VIU and 4treated by open repair. All the 6 cases of posterior distraction defect were treated by anastomotic urethroplasty.

In two cases of short anterior stricture,there was a mild catching of bulbar urethra & bladder neck elevation in one case for which bladder neck incision was done.

Surgery –site of stricture –table -8

Surgery site of stricture		Urethra		
		Anterior	Posterior	Total
bulbomembranous	Count	0	6	6
	% within anterior/ post	0.00%	100.00%	20.00%
	% of Total	0.00%	20.00%	20.00%
Distal bulbar	Count	14	0	14
	% within anterior/ post	58.30%	0.00%	46.70%
	% of Total	46.70%	0.00%	46.70%
Long bulbar	Count	3	0	3
	% within anterior/ post	12.50%	0.00%	10.00%
	% of Total	10.00%	0.00%	10.00%
Proximal bulbar	Count	6	0	6
	% within anterior/ post	25.00%	0.00%	20.00%
	% of Total	20.00%	0.00%	20.00%
No stricture	Count	1	0	1
	% within anterior/ post	4.20%	0.00%	3.30%
	% of Total	3.30%	0.00%	3.30%
Total	Count	24	6	30
	% within anterior/ post	100.00%	100.00%	100.00%
	% of Total	80.00%	20.00%	100.00%

In one case of distal bulbar stricture,there was only a mild narrowing,scope passed with mild negotiation



Pie chart – 7 showing site of stricture in surgery

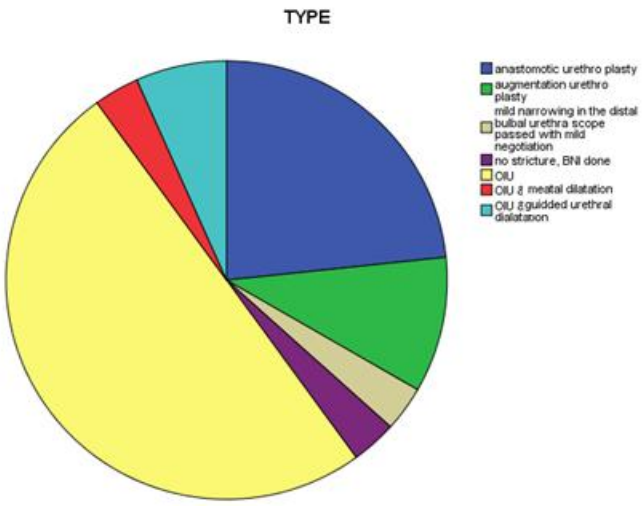
The above pie chart shows the site of the stricture in surgery.In anterior urethral stricture 14 cases were distal bulbar (1 case only mild narrowing), 3 cases were long bulbar and 6 cases were proximal bulbar urethra and in one case there was no stricture. But there was a mild catching in the bulbar urethra and bladder neck elevation.In posterior urethra six cases were obliterative stricture in bulbomembranous junction

TYPE OF SURGERY

Surgery –type –table-9

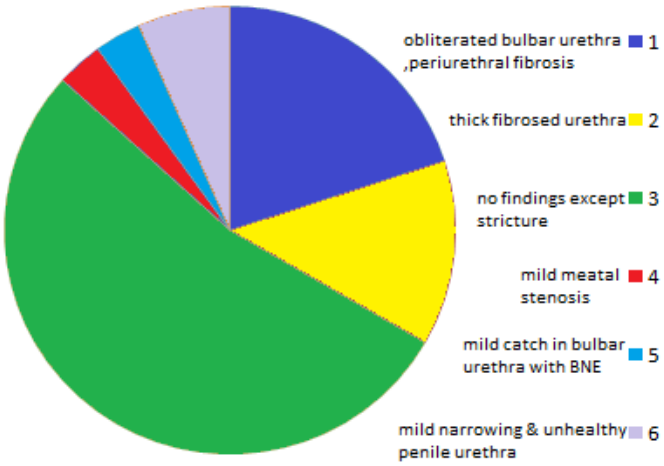
Surgery-type		Urethra		
		Anterior	Posterior	Total
anastomotic urethroplasty	Count	1	6	7
	% within ant/ post	4.20%	100.00%	23.30%
	% of Total	3.30%	20.00%	23.30%
augmentation urethroplasty	Count	3	0	3
	% within ant/ post	12.50%	0.00%	10.00%
	% of Total	10.00%	0.00%	10.00%
mild narrowing in the distal bulbar urethra scope passed with mild negotiation	Count	1	0	1
	% within ant/ post	4.20%	0.00%	3.30%
	% of Total	3.30%	0.00%	3.30%
no stricture, BNI done, mild catching in bulbar urethra	Count	1	0	1
	% within ant/ post	4.20%	0.00%	3.30%
	% of Total	3.30%	0.00%	3.30%
OIU	Count	15	0	15
	% within ant/ post	62.50%	0.00%	50.00%
	% of Total	50.00%	0.00%	50.00%
OIU & meatal dilatation	Count	1	0	1
	% within ant/ post	4.20%	0.00%	3.30%
	% of Total	3.30%	0.00%	3.30%
OIU & guided urethral dilatation	Count	2	0	2
	% within ant/ post	8.30%	0.00%	6.70%
	% of Total	6.70%	0.00%	6.70%
Total	Count	24	6	30
	% within ant/ post	100.00%	100.00%	100.00%
	% of Total	80.00%	20.00%	100.00%

TYPE OF SURGERY



Pie chart – 8 showing the type of surgery.

Among the 24 anterior urethral stricture, endoscopic procedure (VIU) was done for 20 patient's .In these 20 cases, one case showed only mild narrowing and the scope passed with little negotiation. In another case showed mild catching of bulbar urethra with mild bladder neck elevation, for which bladder neck incision was done. 4 cases of stricture of anterior urethra (2cases <1.5cm & 2cases >1.5cm) was managed by open repair (3 augmentation urethroplasty,1anastomotic urethroplasty) 6 PFUDD cases were managed by progressive perineal anastomotic urethroplasty.



Pie chart – 9 showing associated findings in surgery

During the procedure the following findings were noted

2 cases – mild narrowing & unhealthy penile urethra

1 case - mild meatal stenosis

4 cases – thick fibrosed urethra (spongiofibrosis)

6 cases – obliterated bulbar urethra with periurethral fibrosis

1 case – mild catch in the bulbar urethra and mild bladder neck elevation

16 cases – no associated findings other than stricture.

ANALYSIS

The following factors were analyzed.

1. Site
2. Number
3. Length
4. Associated findings

SITE –In anterior urethra the site of stricture in both RUG and MR urethrogram were well co-related with the site in surgery.

In posterior urethra RUG showed only blind ending bulbar urethra and closed bladder neck, but MRU showed the exact site in all the 6cases

NUMBER –In all cases both RUG and MRU showed single stricture.

LENGTH OF STRICTURE

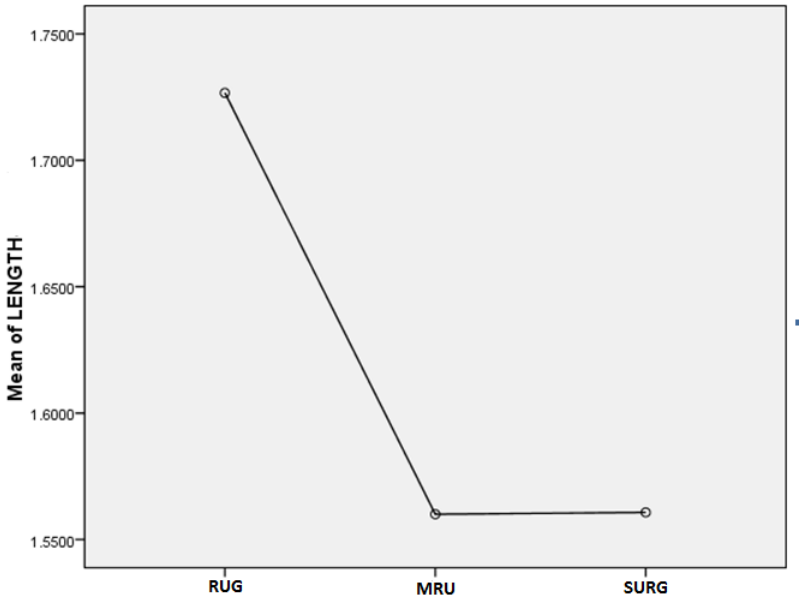
In overall 30cases the mean length of the stricture by RUG, MRU, SURGERY was 1.72, 1.56 and 1.56 cm

The mean length of stricture by RUG, MRU, SURG in anterior stricture cases were 1.19,1.36,1.29 cm

The mean length of stricture by RUG, MRU, SURG in posterior distraction defect cases were 4.08, 2.51, 2.5 cm

Table 10- shows the mean length of the stricture

					95% Confidence Interval for Mean			
	N	Mean	Std. Deviation	Std. Error	Lower Bound	Upper Bound	Minimum	Maximum
RUG	30	1.726667	1.2376099	.2259556	1.264536	2.188798	.5000	4.5000
MRU	30	1.560000	.6387488	.1166190	1.321487	1.798513	.6000	2.9000
SURG	28	1.560714	.6505492	.1229422	1.308458	1.812971	.6000	3.0000
Total	88	1.617045	.8855444	.0943993	1.429417	1.804674	.5000	4.5000



Mean plot curve shows the mean length of the stricture by RUG, MRU, and SURG

PAIRED –T-TEST AND CORRELATION ANALYSIS FOR ANTERIOR STRICTURE

Paired –t-test and correlation analysis for anterior stricture –table -11

		Mean	N	Std. Deviation	Std. Error Mean
Pair 1	RUG-LENGTH & SUR-	1.190909	22	.2876987	.0613376
	LENGTH	1.304545	22	.4466567	.0952275
Pair 2	MRU-LENGTH&SUR-	1.368182	22	.3944693	.0841011
	LENGTH	1.304545	22	.4466567	.0952275

Paired Samples Correlations –table - 11

		N	Correlation	Sig.
Pair 1	RUG-LENGTH& SUR- LENGTH	22	.530	.011
Pair 2	MRU-LENGTH &SUR- LENGTH	22	.833	.000

The above table -11 infers that there was a positive correlation between RUG and SURG length (correlation =0.530) and positive correlation between MRU and SURG (correlation = 0.833).but the measure of agreement between MRU length & SURG length was higher than RUG & SURG length (correlation = 0.833 > 0.530) this clearly indicate MRU length was more agreement with SURG length.

PAIRED –T-TEST AND CORRELATION ANALYSIS FOR POSTERIOR DEFECT

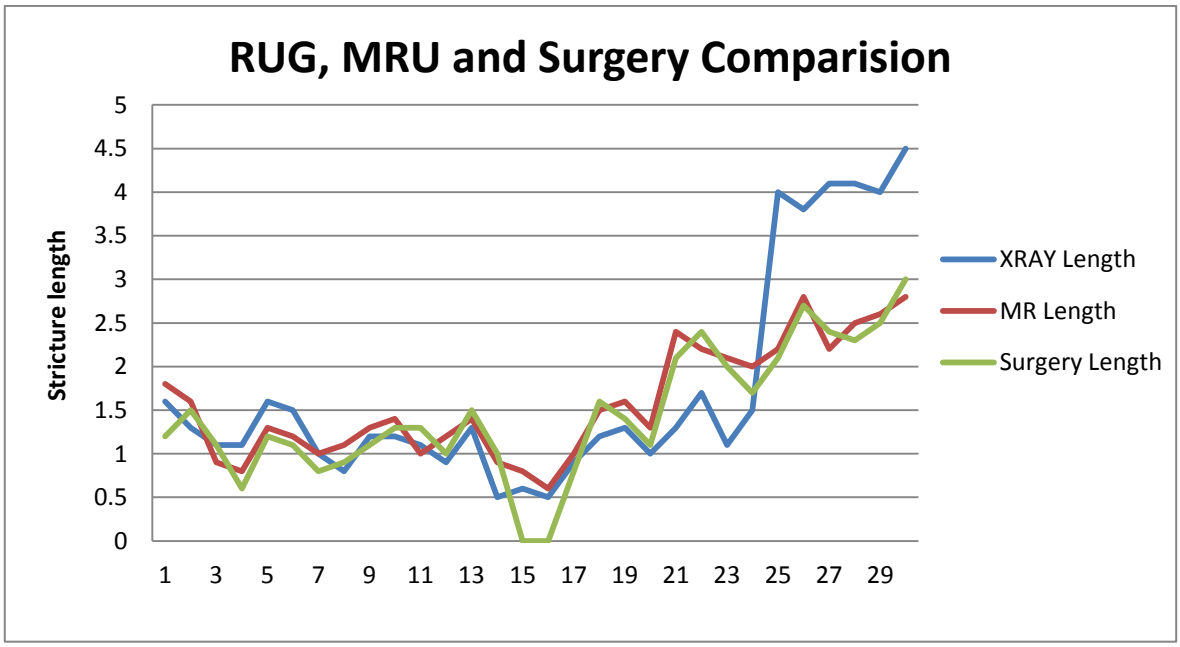
Paired –t-test and correlation analysis for posterior urethral defect –table - 12

		Mean	N	Std. Deviation	Std. Error Mean
Pair 1	LENGTH-RUG	4.083333	6	.2316607	.0945751
	SURG-LENGTH	2.500000	6	.3162278	.1290994
Pair 2	LENGTH-MR	2.550000	6	.2738613	.1118034
	SURG-LENGTH	2.500000	6	.3162278	.1290994

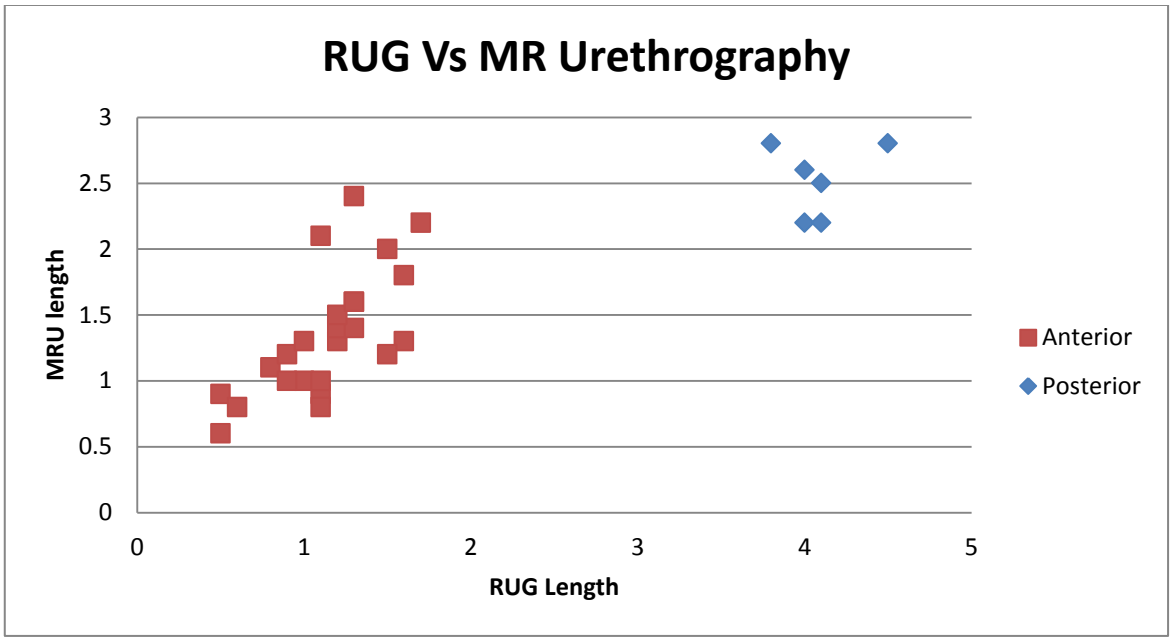
Paired Samples Correlations table – 12

		N	Correlation	Sig.
Pair 1	LENGTH-RUG & SURG-LENGTH	6	.491	.322
Pair 2	LENGTH-MR &SURG- LENGTH	6	.924	.000

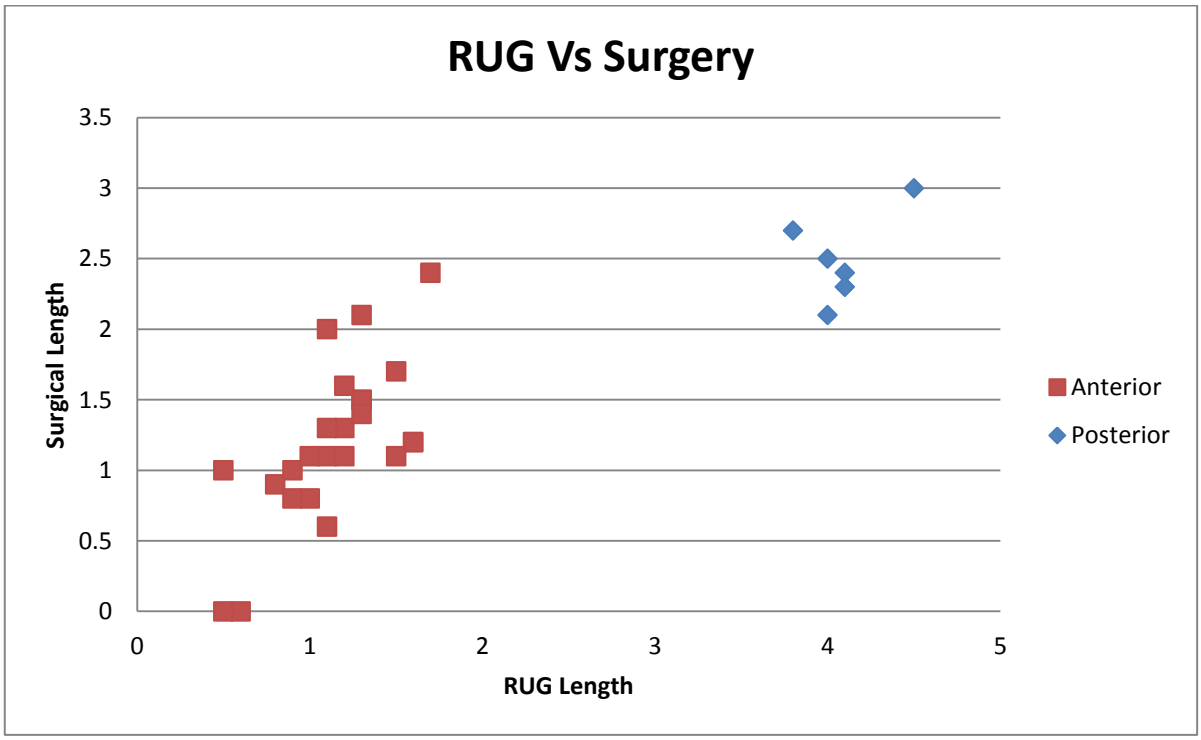
In above table -12-In the posterior distraction defect it showed the measure of agreement between MRU &SURG length was higher than RUG & SURG length (correlation = 0.924>0.491) P =0.000<0.001 and statistically significant



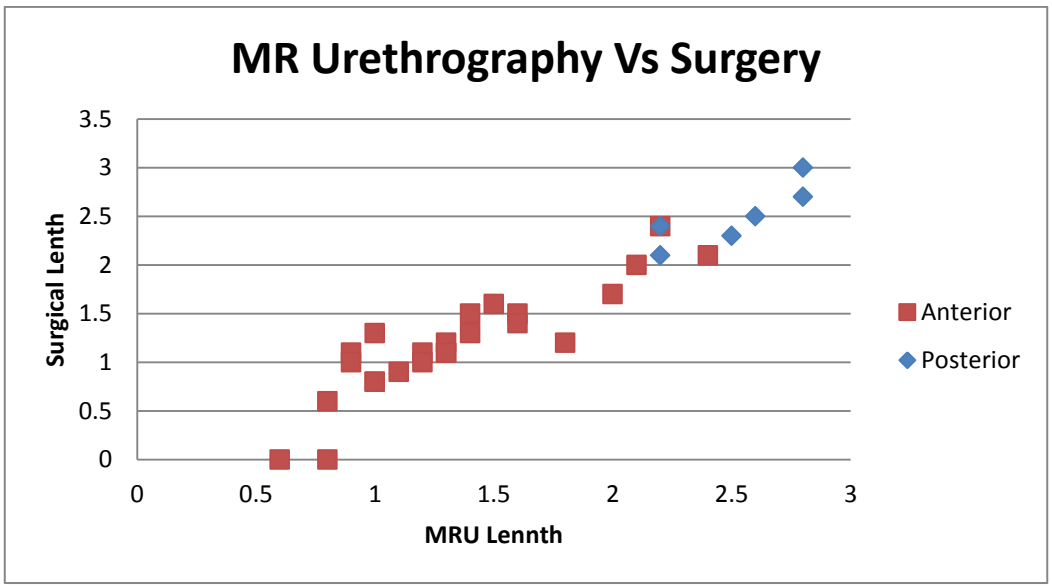
The line graphs show the comparison among RUG, MRU and Surgical length. The MRU length was well correlated with surgical length



The scatter diagram shows RUG length and MRU length was well co-related or minimal difference in anterior urethral strictures but in Posterior urethra there was gross difference in length between RUG and MRU.



The scatter diagram shows RUG length and surgical length was well co-related or minimal difference in anterior urethral strictures but in Posterior urethra there was gross difference in length between RUG and Surgical length



The scatter diagram shows SURG length and MRU was well co-related or minimal difference in Anterior and Posterior urethral strictures.

ASSOCIATED FINDINGS

RUG showed mild penile urethral narrowing in one case which contributes 3.3%, but MRU showed additional findings in 33.3% of cases. It was superior in delineating Spongiofibrosis (image1b, 2b), periurethral fibrosis (image 3b, 4b), and prostatic apex displacement (image 4c).

In 3 cases RUG showed short stricture<1.5cm, but MR showed long stricture>1.5cm with spongiofibrosis. Hence these patients(Two Cases) were managed by urethroplasty(Image 1a & 1b). One case was managed endoscopically in view of minimal spongiofibrosis although length was >1.5 cms

In 6 cases of posterior distraction defect, MR showed accurate length of posterior urethra and associated periurethral fibrosis, prostatic apex displacement. These findings helped to plan the operative approach (Images 3a, 3b, 4a, 4b &4c)

SENSITIVITY &SPECIFICITY BETWEEN RUG AND SURGERY

Crosstab – table-13

			SURGERY TYPE		
			Endo	Open surgery	Total
LEN-GROUP	<1.5cm	Count	17	2	19
		% of Total	56.7%	6.7%	63.3%
	>1.5cm	Count	3	8	11
		% of Total	10.0%	26.7%	36.7%
	Total	Count	20	10	30
		% of Total	66.7%	33.3%	100.0%

Sensitivity	80%
Specificity	85%
Positive Predictive Value	72.73%
Negative Predictive Value	89.47%
Diagnostic Accuracy	83.33%

KAPPA MEASURE OF AGREEMENT IS = 0.634

This above table showed the accuracy of RUG for predicting the type of surgery was about 83.33%

SENSITIVITY & SPECIFICITY BETWEEN MRU AND SURGERY

Crosstab – table-14

			SURGERY TYPE		
			Endoscopy	Open repair	Total
LEN-MR-GROUP	<1.5cm	Count	16	0	16
		% of Total	53.3%	.0%	53.3%
	>1.5cm	Count	4	10	14
		% of Total	13.3%	33.3%	46.7%
	Total	Count	20	10	30
		% of Total	66.7%	33.3%	100.0%

Sensitivity	100%
Specificity	80%
Positive Predictive Value	71.43%
Negative Predictive Value	100%
Diagnostic Accuracy	90.1%

KAPPA AGREEMENT 0.727

This above table showed the accuracy of MRU for predicting the type of surgery was about 90.1%

The sensitivity &specificity for diagnosing stricture by both RUG &MRU was 100% &93.4% both in anterior and posterior urethra

DISCUSSION

The retrograde urethrogram was set as gold standard imaging modality for the diagnosis of stricture urethra in 1910, by Cunningham[3] because it is easily available and a simple technique. But it has certain disadvantages like over or under estimation, radiation effect and does not provide information about spongiofibrosis.

To overcome this limitation, MRI was suggested, according to Garcia-Valtuille,[8] the treatment choice and route of approach depends upon the site, length, spongiofibrosis and associated pathology. Endoscopic repair can be effective for stricture < 1.5 cm without spongiofibrosis. The long stricture > 1.5cm with spongiofibrosis can be treated by open repair either anastomotic or augmentation urethroplasty[26] through perineal route, but complex stricture needs transpubic approach.

This study showed the sensitivity &specificity for diagnosing stricture by both RUG &MRU was 100% &93.4% both in anterior & posterior urethra. whereas the study by Syed Mamun Mahmud et al [6] ,the sensitivity & specificity of RUG for the diagnosis of urethral stricture was 91% &72%and by MRU it was 100%.

The other study by MA El-Ghar et al [13]showed the sensitivity, specificity for diagnosing anterior urethral stricture by RUG was 91% & 90% and 89% & 91.7% for posterior urethra,by MRU it was 91.7% (ant &post). In Sonourethrography the accuracy was 100% in ant urethra, 60% in post urethra.

In this study the accuracy showed by RUG for planning surgery was 83% and by MR urethrogram was 90.1%.But the study by Yasser osman[14] for both RUG and MR urethrogram the accuracy was 85%.

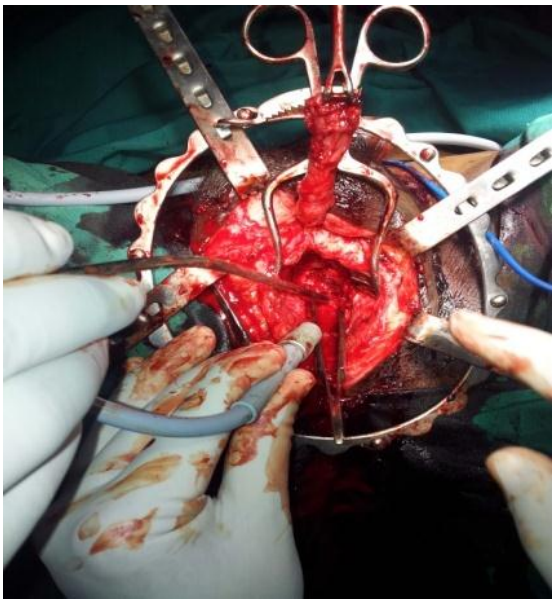
In this study MR urethrogram diagnosed all the cases of anterior and posterior stricture with exact delineation of its length with 100% sensitivity, 93.4% specificity and 90.1% overall accuracy, which was well correlated the study by MA El-Ghar et al [13]

In this study in 6 cases of posterior distraction defect, RUG showed over estimation of defect because of failure of bladder neck to relax. But MR urethrogram showed accurate length and associated findings which helped to plan the surgical approach similar to the study conducted by Sung DJ et al.[16]

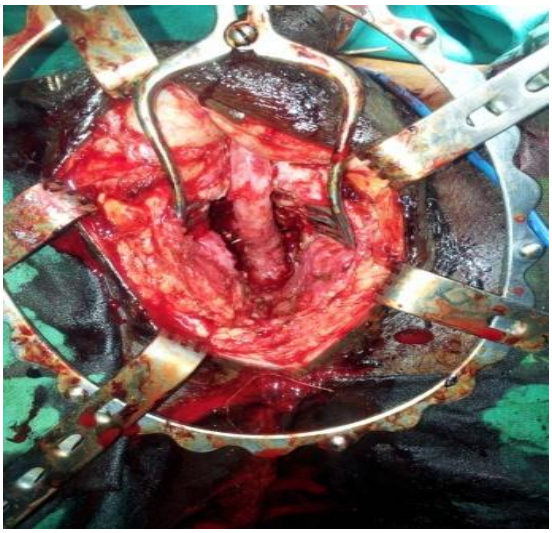
In this small series of patients MR urethrography proved to be a promising technique for evaluating male urethral stricture.It combined the advantages of RUG and Sonourethrography with its few disadvantages of cost effectiveness and its availability.

IMAGES

Anastomotic urethroplasty –
Proximal urethra mobilization.



Anastomotic urethroplasty –
Distal urethra mobilization.



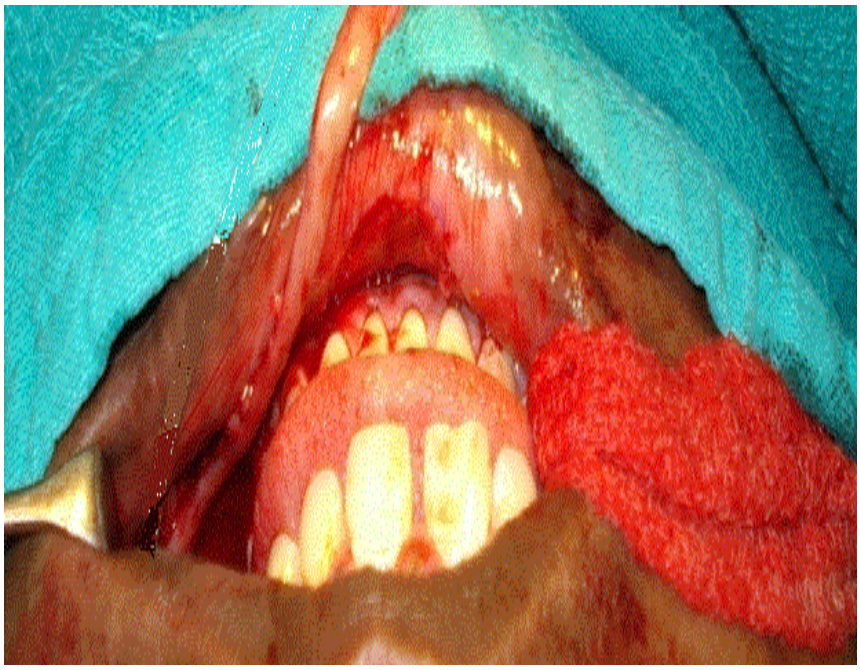
After Anastomosis

The above picture shows per-operative pictures of Anastomotic urethroplasty

The below picture shows the endoscopic view of stricture and Visual internal urethrotomy

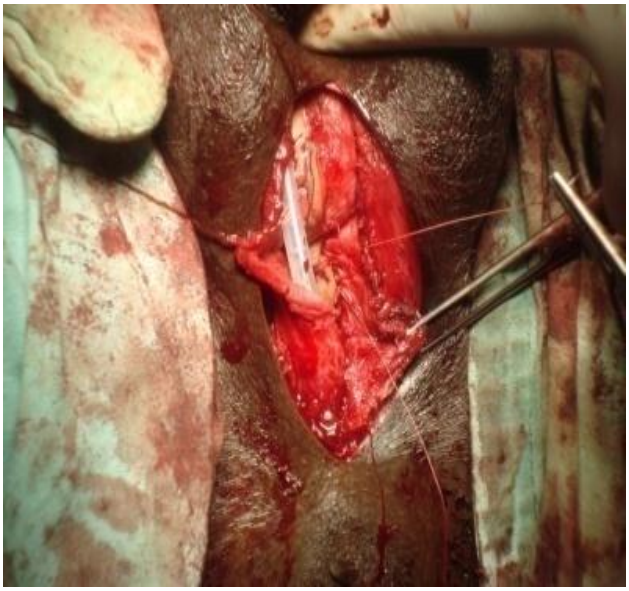
Urethroscopic view of stricture

Visual internal urethrotomy

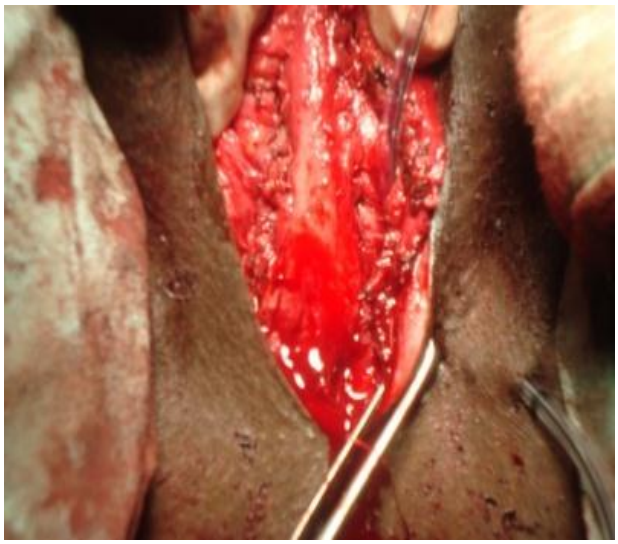


Buccal mucosal graft

The above picture shows the graft taken from the buccal mucosa for augmentation urethroplasty.



Dorsal onlay graft



After augmentation

The above picture shows the per operative picture of augmentation urethroplasty

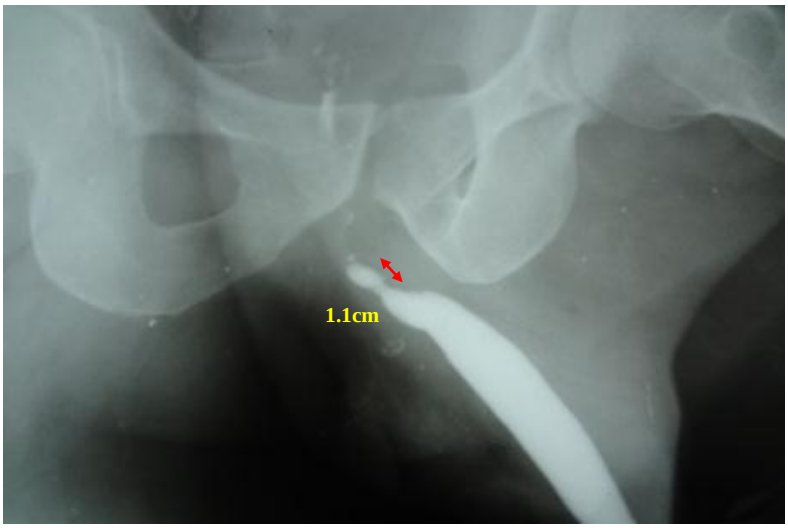


Image-1a

Image-1a- RUG showing 1.1cm short bulbar stricture

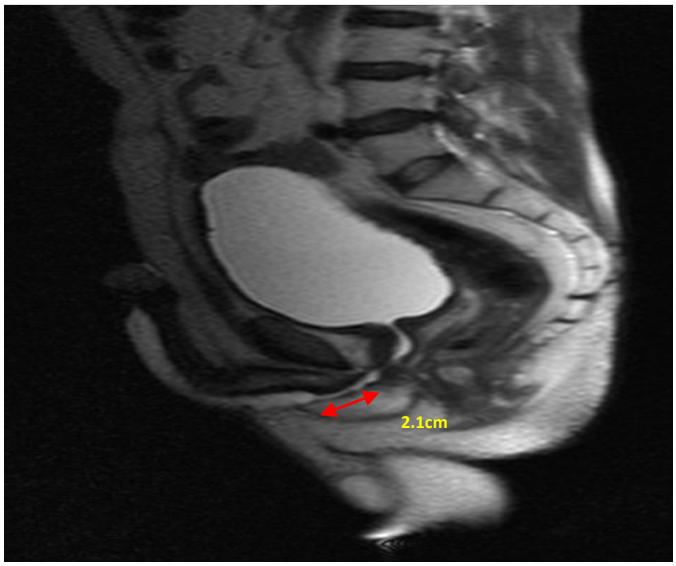


Image-1b

Image-1b –MR urethrography for the same patient showing 2.1cm bulbar stricture with hypointense spongiofibrosis

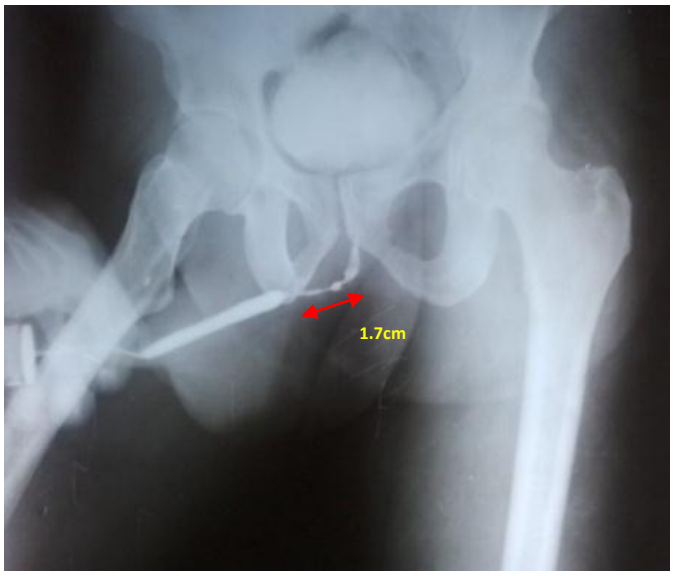


Image 2a

Image 2a –RUG showing long 1.7 cm bulbar stricture.

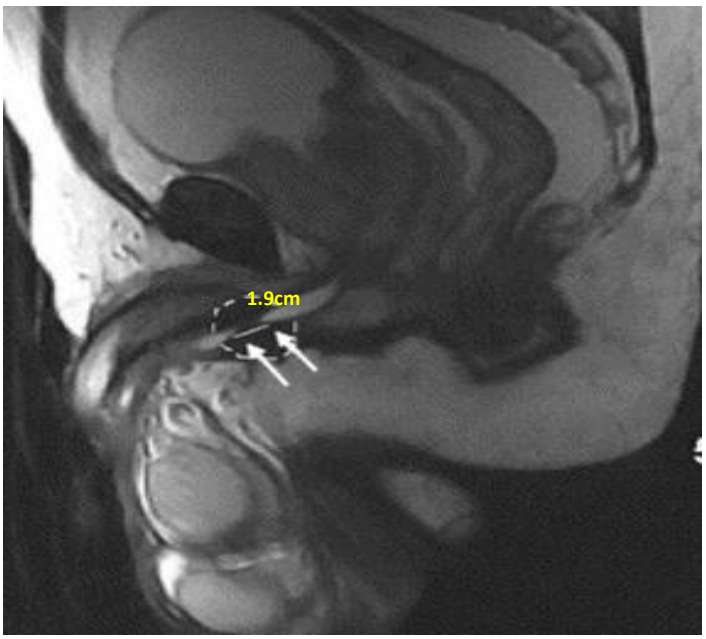


Image 2b

Image 2b –MR urethrography for the same patient showing 1.9cm bulbar stricture With hypointense spongiofibrosis

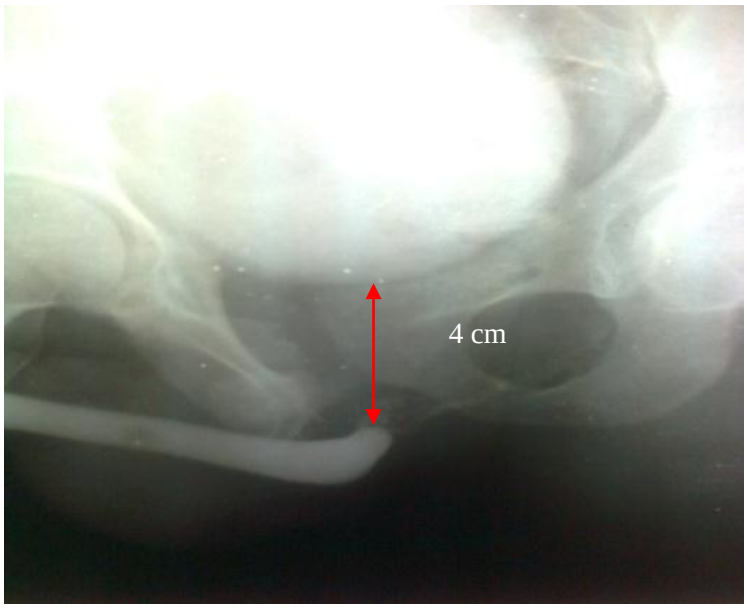


Image 3a

Image 3a- RUG and opposing urethrogram showing 4 cm posterior urethral defect, bladder neck not opened

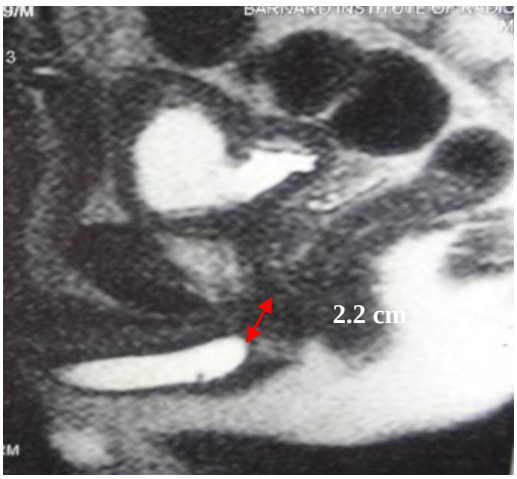


Image 3b

Image 3b- MR urethrogram of above patient showing 2.2 cm bulbo membranous defect with periurethral fibrosis

Image 4a

Image 4a-RUG and opposing urethrogram showing obliterative blind bulbar urethra with 4.1 cm long posterior urethral defect, bladder neck not opened

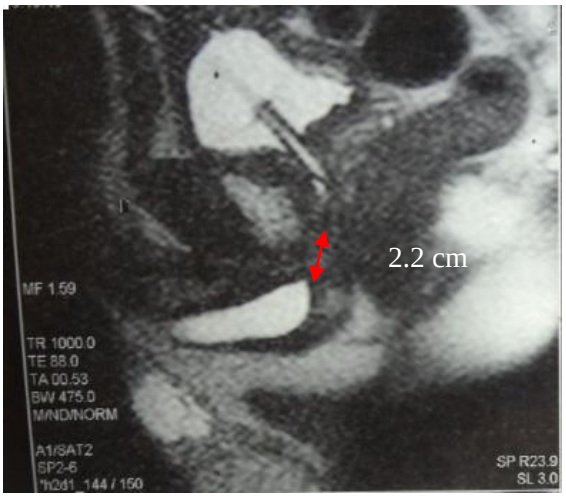


Image 4b

Image 4b - MR urethrogram of above patient showing 2.2 cm bulbo membranous defect with periurethral fibrosis.

Image 4c

Image 4c – MR coronal image showing displacement of the prostate apex.

CONCLUSION

In summary, our study has demonstrated that MR urethrography is a very useful and promising noninvasive technique for the evaluation of male anterior urethral stricture and posterior urethral distraction defect for planning the surgical approach.

It was superior than RUG for the accurate assessment of length of stricture and extent of spongiofibrosis in anterior urethral stricture.

In posterior urethral defect MR urethrography, correctly estimates the length of the stricture, degree of prostatic displacement and delineates the site & density of scar tissue, which helps to plan the surgical approach

This procedure is also well tolerated by patients, who are allergic to iodinated contrast during RUG.

A

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ANNEXURE I
PROFORMA

KMCH/GRH

Name : Date:
Age : Sex: Op No: IP No:
Phone No :

PRESENT ILLNESS:

- LUTS – Obstructive/Irritative
- Dysuria,frequency,urgency,hesitancy,intermittency,thin stream,strain to void
- Fever
- H/O pelvic trauma
- H/O previous surgery/ instrumentation
- Past H/O DM / HT/ COPD

O/E:

- Fever, Pallor
- BP
- Pulse
- Abdomen
  - Bladder distended/not
  - Genitalia
  - DRE – Prostate size, consistency, nodule

INVESTIGATION

- Urine –
  - alb
  - Sug
  - Deposits
- Urine c/s
- Hemogram
- Sr.creatinine , Urea
- Blood sugar
- Xray KUB
- USG KUB
- UROFLOMETRY

- Retrograde urethrogram
- MR urethrogram
- Urethroscopy/Urethroplasty findings

ANNEXURE - II

MASTER CHART

SL.NO	NAME	AGE	I.P NUMBER	ASCENDINIG URETHROGRAPHY					MR URETHROGRAPHY					SURGERY					
				LENGTH	LEN-GROUP	SITE	NUM	OTHER FINDINGS	LENGTH	LEN-GROUP	SITE	NUM	OTHER FINDINGS	TYPE	LENGTH	LEN-GROUP	SITE	NUM	OTHER FINDINGS	CAUSE
1	Manickam	49	106902/GRH	1.6 cm	1	distal bulbar	1	no	1.8 cm	1	distal bulbar	1	no	OIU&GUD	1.2 cm	0	distal bulbar	1	penile urethra unhealthy and mild narrowing	inflammatory
2	Bose	32	1421/KMCH	1.3 cm	0	distal bulbar	1	no	1.6 cm	1	distal bulbar	1	no	OIU	1.5 cm	1	distal bulbar	1	nil	inflammatory
3	Natesan	40	2282/KMCH	1.1 cm	0	distal bulbar	1	no	0.9 cm	0	distal bulbar	1	no	OIU	1.1cm	0	distal bulbar	1	nil	straddle injury
4	Venkatesh	32	18396/GRH	1.1cm	0	proximal bulbar	1	no	0.8cm	0	proximal bulbar	1	no	OIU	0.6cm	0	proximal bulb	1	nil	straddle injury
5	Nagaiah	40	9422/KMCH	1.6 cm	1	distal bulbar	1	no	1.3cm	0	distal bulbar	1	no	OIU	1.2cm	0	distal bulbar	1	nil	inflammatory
6	Mohammed mustafa	48	112593/GRH	1.5 cm	1	distal bulbar	1	narro pen ure	1.2cm	0	distal bulbar	1	narro pen ure	OIU&GUD	1.1cm	0	distal bulbar	1	mild penile urethra narrowing & unhealthy	inflammatory
7	Dharmalingam	35	2069/KMCH	1 cm	0	proximal bulbar	1	no	1cm	0	proximal bulbar	1	no	OIU	0.8cm	0	proximal bul	1	nil	inflammatory
8	Jeyaraman	53	22878/GRH	0.8 cm	0	proximal bulbar	1	no	1.1 cm0	0	proximal bulbar	1	no	OIU	0.9cm	0	proximal bulb	1	nil	catheterization
9	Shanmugam	46	7895/KMCH	1.2cm	0	distal bulbar	1	no	1.3cm	0	distal bulbar	1	no	OIU	1.1cm	0	distal bulbar	1	nil	straddle injury
10	Srinivasan	41	6832/KMCHAA	1.2cm	0	distal bulbar	1	no	1.4cm	0	distal bulbar	1	no	OIU	1.3cm	0	distal bulbar	1	nil	traumatic catheterization
11	Saddique	30	3257/GRH	1.1 cm	0	proximal bulbar	1	no	1cm	0	proximal bulbar	1	no	OIU	1.3cm	0	proximal bul	1	nil	instrumentation
12	Mahadevan	40	7143/KMCH	0.9cm	0	distal bulbar	1	no	1.2cm	0	distal bulbar	1	no	OIU	1cm	0	distal bulbar	1	nil	instrumentation
13	Krishnan	47	21203/GRH	1.3cm	0	distal bulbar	1	no	1.4cm	0	distal bulbar	1	no	OIU & meat dila	1.5cm	1	distal bulbar	1	mild meatal narrowing	inflammatory
14	Kumaresan	24	3312/KMCH	0.5cm	0	distal bulbar	1	no	0.9cm	0	distal bulbar	1	no	OIU	1 cm	0	distal bulbar	1	nil	inflammatory
15	Jeganathan	39	2991/KMCH	0.6 cm	0	distal bulbar	1	no	0.8cm	0	distal bulbar	1	no	mild narrow dist bulb ure	0	0	distal bulbar	0	nil	traumatic catheterization
16	Chakarabani	55	7251/KMCH	0.5 cm	0	distal bulbar	1	no	0.6 cm		distal bulbar	1	no	no stricture,mild BNE, BNI done	0	o	distal bulbar	0	mild bladder neck elevation,catch in the bulbar urethra	inflammatory
17	Sankaran	31	997999/GRH	0.9cm	0	proximal bulbar	1	no	1 cm	0	proximal bulbar	1	no	OIU	0.8cm	0	proximal bul	1	nil	inflammatory
18	Veerappan	40	35691/GRH	1.2cm	0	proximal bulbar	1	no	1.5cm	1	proximal bulbar	1	no	OIU	1.6cm	1	proximal bul	1	nil	instrumentation
19	Perumal	50	1861/KMCH	1.3cm	0	distal bulbar	1	no	1.6cm	1	distal bulbar	1	no	OIU	1.4cm	0	distal bulbar	1	nil	traumatic catheterization
20	Elumalai	58	18916/GRH	1cm	0	distal bulbar	1	no	1.3cm	0	distal bulbar	1	no	OIU	1.1cm	0	distal bulbar	1	nil	instrumentation
21	Samy	55	1163/KMCH	1.3cm	0	distal bulbar	1	no	1.8 cm	1	distal bulbar	1	spon fib +	augmentation urethro plasty	2.1cm	1	distal bulbar	1	corpus spongio fibrosis urethra appears thick and fibrosed	instrumentation
22	Subbaiah	41	3831/GRH	1.7cm	1	long bulbar urethra	1	no	1.9cm	1	long bulbar urethra	1	spon fib +	augmentation urethro plasty	2.2cm	1	long bulbar	1	spongio fibrosis, urethra thick and fibrosed	inflammatory
23	Prabhu	44	11602/GRH	1.1cm	0	distal bulbar	1	no	2.1cm	1	long bulbar urethra	1	spon fib +	augmentation urethro plasty	2cm	1	long bulbar	1	bulbar urethra unhealty thick and,fibrosed	straddle injury
24	Panneer	37	3542/KMCH	1.5cm	1	proximal bulbar	1	no	2cm	1	long bulbar urethra	1	spon fib +	anastomotic urethro plasty	1.7cm	1	long bulbar	1	severe spongio fibrosis	blunt injury perineum
25	Raja	50	1227/KMCH	4cm	1	blind end bul ure	1	blad.neck closed	2.2cm	1	bulbo membranou	1	periure fib	anastomotic urethro plasty	2.1cm	1	bulbo memb	1	bulbo membranous urethra obliterated with surrounding area fibrosis	PFUDD
26	Sethuraman	28	112081/GRH	3.8cm	1	blind end bul ure	1	blad.neck closed	2.8cm	1	bulbo membranou	1	periure fib, post displa pros	anastomotic urethro plasty	2.7cm	1	bulbo memb	1	bulbo membranous urethra obliterated with surrounding area fibrosis	PFUDD
27	Vetri	19	119535/GRH	4.1cm	1	blind end bul ure	1	blad.neck closed	2.2cm	1	bulbo membranou	1	periure fib, post displa pros	anastomotic urethro plasty	2.4cm	1	bulbo memb	1	bulbo membranous urethra obliterated with surrounding area fibrosis	PFUDD
28	Murugan	49	111590/GRH	4.1cm	1	blind end bul ure	1	blad.neck closed	2.5cm	1	bulbo membranou	1	periure fib+	anastomotic urethro plasty	2.3cm	1	bulbo memb	1	obliterated bulbar urethra with surrounding area fibrosis	PFUDD
29	Richard	38	3009/KMCH	4cm	1	blind end bul ure	1	blad.neck closed	2.6cm	1	bulbo membranou	1	periure fib+	anastomotic urethro plasty	2.5cm	1	bulbo memb	1	obliterated bulbar urethra with surrounding area fibrosis	PFUDD
30	Jothiraj	30	1143/KMCH	4.5cm	1	blind end bul ure	1	blad.neck closed	2.8cm	1	bulbo membranou	1	periure fib, post displa pros	anastomotic urethro plasty	3cm	1	bulbo memb	1	obliterated bulbar urethra with surrounding area fibrosis	PFUDD

INSTITUTIONAL ETHICAL COMMITTEE
GOVT.KILPAUK MEDICAL COLLEGE,
CHENNAI-10
Ref.No.1463/ME-1/Ethics/2012 Dt:08.05.2012.
CERTIFICATE OF APPROVAL

The Institutional Ethical Committee of Govt. Kilpauk Medical College, Chennai reviewed and discussed the application for approval "A study of Comparative study between retrograde urethrogram and MR urethrogram in evaluating male urethral strictures" submitted by Dr.R.Sukumar, MCh Genito Urinary Surgery, PG Student, KMC, Ch-10

The Proposal is APPROVED.

The Institutional Ethical Committee expects to be informed about the progress of the study any Adverse Drug Reaction Occurring in the Course of the study any change in the protocol and patient information /informed consent and asks to be provided a copy of the final report.

GOVT. KILPAUK MEDICAL COLLEGE
26 JUL 2012
Kilpauk, Chennai-10.

26/7/12
CHAIRMAN,
Ethical Committee
Govt.Kilpauk Medical College,Chennai

சுய ஒப்புதல் பழவம்

ஆய்வு செய்யப்படும் தலைப்பு:

கீழ்பாக்கம்மருத்துவக் கல்லூரி

பங்கு பெறுபவரின் பெயர் :

பங்கு பெறுபவரின் வயது :

பங்கு பெறுபவரின் எண் :

பங்கு பெறுபவர் இதனை (✓) குறிக்கவும்.

மேலே குறிப்புட்டுள்ள மருத்துவ ஆய்வின் விவரங்கள் என்க்கு விளக்கப்பட்டது. என்னுடைய சந்தேகங்களை கேட்கவும், அதற்கான தகுந்த் விளக்கங்களை பெறவும் வாய்ப்பளிக்கப்பட்டுள்ளது என அறிந்து கொண்டேன்.	☐
நான் இவ்வாய்வில் தன்னிச்சையாக தான் பங்கேற்கிறேன். எந்த காரணத்தின்லோ எந்த சட்டசிக்கலுக்கும் உட்படாமல் நான் இவ்வாய்வில் இருந்து வில்கி கொள்ளலாம் என்றும் அறிந்தும் கொண்டேன்.	☐
இந்த ஆய்வு சம்பந்தமாகவோ, இதை சார்ந்து மேலும் ஆய்வு மேற்கொள்ளும் போதும் இந்த ஆய்வில் பங்கு பெறும் மருத்துவர் என்னுடைய மருத்துவ அறிக்கைகளை பார்ப்பதற்கு என் அனுமதி தேவையில்லை என அறிந்து கொள்கிறேன்.	☐
இந்த ஆய்வின் மூலம் கிடைக்கும் தகவலையோ, முடிவையோ பயன்படுத்திக் கொள்ள மறுக்கமாட்டேன்.	☐
இந்த ஆய்வில் பங்கு கொள்ள ஒப்புக் கொள்கிறேன். இந்த ஆய்வை மேற்கொள்ளும் மருத்துவ அணிக்கு உண்மையுடன் இருப்பேன் என்றும் உறுதியளிக்கிறேன்.	☐
இந்த ஆய்வில் ஒருமுறை 5 மி இரத்தம் பரிசோதனைக்காக எடுத்துக் கொள்ளப்படும் என்பதை அறிவேன்.	☐

பங்கேற்பவரின் கையொப்பம் _____ இடம் _____ தேதி

இடம் _____ தேதி _____

பங்கேற்பவரின் பெயர் மற்றும் விலாசம்

சாட்சியாளரின் கையொப்பம்

இடம் _____ தேதி _____

சாட்சியாளரின் பெயர் மற்றும் விலாசம்

ஆய்வாளரின் கையொப்பம்

இடம் _____ தேதி _____

ஆய்வாளரின் பெயர் _____